IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/800,031
Applicant	:	Tara Lynn BIELSKI, et al.
Filed	:	March 15, 2004
TC/A.U.	:	4173
Examiner	:	Tristan J. Mahyera
Docket No.	:	1592-473
Customer No.	:	06449
Confirmation No.	:	6868

Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION under 37 C.F.R. §1.131

We, Tara Lynn Bielski and Kerry Roy Benson, declare as follows:

1. We are the same Tara Lynn Bielski and Kerry Roy Benson named as inventor on the above-referenced U.S. patent application.

2. Attached hereto as Exhibit 1 is a copy of Master Formula pages for Formula No.: 3422-S05-5, and Exhibit 2 is a copy of Manufacturing Directions pages for Formula No.: 3422-S05-5. The Master Formula pages and the Manufacturing Directions pages were used to produce Batch No: R1K1068 of Formula No.: 3422-S05-5.

3. The originals of these two documents including the handwritten entries were prepared and/or approved prior to August 25, 2003. The photocopies attached hereto are true and accurate copies of the original pages, with the exception that the actual dates of the entries on the Master Formula pages and the Manufacturing Directions pages, and other dates referenced on the pages, have been redacted in the copies provided. After these Master Formula pages and the Manufacturing Directions pages were prepared and

approved, the handwritten entries that appear on these documents were made, signed and dated contemporaneously with the work described therein.

4. The Master Formula pages describe the composition of the formulation containing nitrofurantoin monohydrate and macrocrystals, which falls within the scope of claims of the present application, and the Manufacturing Directions pages describe how to produce this formulation.

5. Specifically, Exhibit 1 consists of 8 pages[1] from the Master Formula, which were prepared under the direction and control of Tara Lynn Bielski and approved by a co-inventor, Kerry Roy Benson. The first page of Exhibit 1 shows information on nitrofurantoin monohydrate/macrocrystals capsules. Each of these capsules contains two tablets comprising 75 mg of nitrofurantoin monohydrate and one tablet comprising 25 mg of nitrofurantoin macrocrystal. Pages 2-5 show that the formulation of nitrofurantoin monohydrate comprises 40.125 mg/unit of nitrofurantoin monohydrate, 40.125 mg/unit of hydroxypropyl methylcellulose, 40.0 mg/unit of sodium alginate and 40.0 mg/unit of alginic acid. The formulation information on pages 3-4 corresponds to Example 1 of the present application. Pages 7-8 show that the formulation of nitrofurantoin macrocrystal comprises 25.0 mg/unit of nitrofurantoin macrocrystals. This formulation information corresponds to Example 2 of the present application.

6. Exhibit 2 consists of 45 pages from the Manufacturing Directions, which were prepared under the direction and control of Tara Lynn Bielski and approved by a co-inventor, Kerry Roy Benson. Pages 9-29 show the instructions on producing tablets containing nitrofurantoin monohydrate formulation which also comprises hydroxypropyl methylcellulose, sodium alginate and alginic acid. The instructions describe granulation/drying (pages 8-18), milling (pages 19-21), blending (pages 22-24) and compression (pages 25-29) procedures. Pages 30-53 describe the instructions for producing tablets containing nitrofurantoin macrocrystals, which consist of instructions

[1] While the Master Formula and the Manufacturing Directions show page numbers in a box appearing the upper right corner of each page, Exhibits 1 and 2 also include pages without such page numbers. Thus, the page numbers indicated in this Declaration are those counting both unnumbered signature pages and the numbered Master Formula and Manufacturing Direction pages.

on blending (pages 30-32), milling (pages 33-34), final blending (pages 35-37) and compression (pages 38-42) procedures. Pages 43-53 show the instructions for encapsulation of the two types of tablets for producing nitrofurantoin monohydrate/macrocrystals capsules. While these instructions are in far more detail because they were used for scale-up testing than what was described in the present application, they clearly evidence that the method for producing the formulation claimed in the present application were completed prior to August 23, 2003.

7. I further declare the all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

Tara Lynn Bielski

Tara Lynn Bielski

06-09-08

Date

Kerry Roy Benson

Kerry Roy Benson

06/10/08

Date